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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,531	11/28/2000	Ari Derowe	088/01925	5181

26418 7590 09/17/2004

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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,531

Applicant(s)

DEROWE ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 233-248 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 233-248 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/8; 5/7, 18, 21/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of group III in the reply filed on 5/26/04 is acknowledged. The traversal is on the ground(s) that since all four groups relate to hole punchers, they should all be classified in the same sub-class and examiner should consider all four group because they are related and in the same subclass. This is not found persuasive because the applicant had not proven that these inventions are not distinct for the reasons given in the previous office action and that the inventions do not include divergent subject that acquire a separate status in the art. Applicant must provide reasons why the groups of invention are not distinct. All of the inventions can be related as being directed to a common subject matter and classified in the same sub-class. However, the common subject matter may be distinct from each other that require different status in the art due to its use or structure. For example, if the hole punchers can have different structures causing different effects, those hole punchers are considered as distinct from each other. In order to overcome the restriction requirement, Applicant should state for the record that all hole punchers in the four groups are the same puncher, and that there is only one way or method for using that puncher.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 233, 234, 236-248 are rejected under 35 U.S.C. 102(b) as being anticipated by Gifford, III et al. (5,695,504). Gifford, III et al. disclose: a method of providing a connector to a blood vessel, comprising all the steps as claimed (see figs. 4-5G, col. 16, line 49 to col. 19, line 67 for each step). Hole puncher (118), a connector (102), spike (116), sub-assembly/surrounding sheaths (137), and tissue engager (136).

In regard to claim 233, providing a distal end of hole puncher (118) adjacent a blood vessel (see figs. 4-5F); punching a hole in the blood vessel (5C-5D); transporting a connector (102) including spikes (116, 105) through a lumen of the hole puncher, while the distal end of the hole puncher is adjacent to the blood vessel (see figs. 5F-6C).

In regard to claim 234, pressing the hole puncher against the outer wall of the blood vessel (5C-5D).

In regard to claim 235, transfixing the at least one spike through the wall of the blood vessel (Fig. 5A-5B)

In regard to claim 236, removing a sub-assembly of the hole puncher from a channel of the hole puncher (5C-5E), transporting the connector through the channel from which the sub-assembly was removed (5F-6C).

In regard to claim 237, removing the central cutter (137) and a surrounding sheath (125) see figure 5G.

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In regard to claim 238, removing the central cutter while surrounding sheath remains with an end adjacent the blood vessel (fig. 5E).

In regard to claim 239, transporting the connector (102) through the lumen of the hole puncher while the hole puncher is in contact with the blood vessel (5F).

In regard to claims 240-242, providing a hole puncher (118), a tissue engager (101), and a surrounding sheath (125), punching a hole (fig. 5D. Note: utilizing the surrounding sheath and the cutter 137 and 136), removing the tissue engager from the hole puncher while the surrounding sheath (125) remains in the vicinity of the blood vessel (inherent); transporting a tool/connector (102) than the tissue engager through the channel (fig. 5F); the connector comprising spike (116).

In regard to claim 243, punching the hole is performed utilizing both the tissue engager and the surrounding sheath (fig. 5C-D).

In regard to claims 244-245, tissue engager (101) having an indent adapted to engage a wall of the vessel (see the shape of 105 having indent area receiving wall vessel) and a sharp distal end (inherent).

In regard to claim 245-248, the language "adapted" in claim 245 and 248 and "rotatable" in claims 246-247 are functional statements and have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Gifford, III et al.'s device which is capable of being used as claimed if one desires to do so.

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***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731  
August 20, 2004

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

9/15/04